

Montana Working Group to Improve Access to Clinical Trials
Consensus Agreement for Healthcare Coverage of
Routine Patient Care Costs Associated with Oncology Clinical Trials
DRAFT DEFINITIONS

I. Cancer Clinical Trials Definitions

- 1.1 The group agreed to adopt the American Society of Clinical Oncology's definition of patient oriented research:
"Clinical investigation in oncology is hypothesis-driven research that employs measurements in whole patients or normal human subjects, in conjunction with laboratory measurements as appropriate, on the subjects of clinical biology, natural history, prevention, screening, diagnosis, therapy or epidemiology of neoplastic disease".
- 2.1 After careful laboratory testing for safety and effectiveness, new therapies are evaluated in people during three phases.
 - 2.1.1 Phase I trials determine toxicities through a continuum of modest dosing to determine safe levels for human subjects. Generally speaking, a trial is considered Phase I if no standard dosing has been developed and no clear understanding of side effects has been established.
 - 2.1.2 Phase II trials begin to evaluate the effectiveness of the treatment. Generally speaking unless a trial contains some evaluation of effectiveness, it will not be considered a Phase II trial.
 - 2.1.3 Phase III trials compare two or more appropriate treatments to evaluate relative efficacy and therapeutic value.

The guidelines in this document are applicable to Phase II and Phase III clinical trials.

- 3.1 Participation in a Phase I trial will not in and of itself effect or revoke other covered services.
- 3.2 Only those clinical trials that have the potential of therapeutic benefit for patients will be considered for coverage.

II. Qualifications Required For "Approved" or "Deemed Status" Clinical Trial Classification

A clinical research study will be considered worthy of support if all of the following apply:

- 1.1 The institution/investigator/team performing the cancer clinical trial adheres to accepted Office of Human Research Protection (OHRP)/National Institute of Health (NIH)/Food and Drug Administration (FDA) procedural and ethical standards pertaining to conflict of interest and consistent protection of human subjects including:
 - 1.1.1 Thoroughness of an independent peer review for scientific validity,
 - 1.1.2 Review and approval by an Institutional Review Board (IRB),
 - 1.1.3 Processes to identify, avoid, and disclose conflicts of interest,
 - 1.1.4 Policies prohibiting payment for patient recruitment beyond reasonable reimbursement for administrative costs incurred and
 - 1.1.5 Policies that prohibit any actions intended to inappropriately influence the review process.
- 2.1 The IRB/institution has written policies to preclude investigators and team members directly responsible for patient selection in a clinical trial, the informed consent process and/or clinical management of a trial from any influence by material enrichment.
 - 2.1.1 These policies shall include review, oversight and appropriate disclosure of potential conflicts of interest that may interfere with appropriate attention to patient care.
- 3.1 The institution shall have policies that would prohibit censorship of clinical trial results by the industry sponsor.
 - 3.1.1 These policies prohibit the industry sponsor reviewer to change, amend or otherwise modify the published outcomes.
 - 3.1.2 These policies prohibit industry sponsor influence on the clinical trial's publication.
- 4.1 Treatment is provided with therapeutic intent
- 5.1 Treatment is being provided pursuant to an oncologic or malignant hematologic clinical trial sponsored or approved by one or more of the following:
 - 5.1.1 One of the National Institutes of Health (NIH),
 - 5.1.2 A NIH cooperative group, or a NIH center;
 - 5.1.3 At, or under the auspices of, an NCI designated Comprehensive Cancer Center
 - 5.1.4 The Food and Drug Administration (FDA) in the form of an investigational new drug (IND) or new device (IDE) exemption

- 5.1.5 The Department of Defense (DOD)
 - 5.1.6 The Department of Veterans Affairs (VA)
 - 5.1.7 Health Care Financing Administration (HCFA),
 - 5.1.8 Agency for Healthcare Research and Quality (AHRQ),
 - 5.1.9 Center for Disease Control (CDC);
 - 5.1.10 A qualified non-governmental research entity as identified in guidelines issued by individual NIH Institutes for center support grants;
- 6.1 The facility and personnel providing the treatment are capable of doing so by virtue of their experience or training.
 - 7.1 The available clinical or pre-clinical data provide a reasonable expectation that the protocol treatment will be at least as efficacious as non-investigational therapy.
 - 8.1 Coverage applies to therapeutic Phase II and Phase III trials meeting these criteria.
 - 9.1 Coverage applies to those enrolled in deemed clinical trials as defined above.

III. Health Plan Discretion

- 1.1 Health plans may grant “deemed status” to investigators or institutions when it determines that the investigator or institution follows and is committed to the principles represented in this document.
- 2.1 Health plans may revoke “deemed status” to an investigator or institution when it determines that the investigator or institution has abused its privileges or violated principles represented in this document.
- 3.1 Clinical trials related to cancer prevention and/or performed at institutions not listed above may be covered outside the scope of this agreement by individual health plans according to their individual policies and procedures.

IV. Costs Associated With Cancer Clinical Trials

Funding for cancer clinical trials, which covers the cost of protocol development and data collection traditionally comes from a variety of sources including pharmaceutical companies, research institutions and government agencies. (Hereafter referred to as “sponsors”) Support for patient care provided in cancer clinical trials is not generally included in this funding.

There are five components of costs associated when conducting clinical trials.

- 1.1 **The administrative costs of the study** are borne by the sponsoring organizations and include:
 - 1.1.1 Data gathering,
 - 1.1.2 Statistical study,
 - 1.1.3 Regulatory requirements,
 - 1.1.4 Contractual agreements,
 - 1.1.5 Meetings and travel.
- 2.1 **The routine patient care costs** (conventional care) shall be provided by the patient's health plan.
 - 2.1.1 Routine patient care costs are items or services that are typically covered benefits when provided outside a clinical trial.
 - 2.1.2 "Routine" services include services that would be approved for coverage under the policy, even when delivered within the context of a clinical trial.
 - 2.1.3 Health plans shall provide coverage for routine patient care costs incurred for drugs and devices provided to the member during the clinical trial provided that those drugs or devices have been approved for sale by the FDA, and to the extent those drugs or devices are not provided or paid for by the sponsor of the clinical trial, or the manufacturer, distributor, or provider of that drug or device.
- 3.1 **The costs associated in the delivery of the investigational agent** shall be borne by the health plan.
 - 3.1.1 Services required solely for the provision of the investigational item shall be provided in accordance with the benefits of the patient's health plan. Coverage would include procedures, drugs or devices approved for coverage for any medical indication.
 - 3.1.2 The clinically appropriate monitoring of the effects of the item or service should be considered routine patient care costs.
 - 3.1.3 The prevention of complications of the item or service should be considered routine patient care costs.
 - 3.1.4 This coverage shall include payment for reasonable and medically necessary services necessary to administer the drug or use the device under evaluation in the clinical trial.
- 4.1 **Costs incurred for patient care generated specifically by the cancer clinical trial** shall be borne by the clinical trial sponsor.

- 4.1.1 Examples of these are costs for additional medication, laboratory studies, or diagnostic imaging.
- 4.1.2 The health plan's coverage of "routine costs" would *not* include non-FDA approved drugs or devices or unapproved medical procedures.
- 4.1.3 Coverage would *not* include diagnostic tests that are performed for investigative purposes but not necessary for the patient's medical management.
- 4.1.3 It would also not include services beyond the scope of the subscriber's contract.

5.1 **Costs of treating adverse side effects** experienced during treatment should be borne by the clinical trial sponsor. The clinical trial sponsor would be expected to cover medical care needed to treat any complications which were probably arising from the investigational service, when the medical services provided are otherwise covered under the subscriber contract.

- 5.1.1 It is recognized that while quality trials are designed with the utmost attention to patient safety, complications can occur when patients are participating in a clinical trial.
- 5.1.2 It is reasonable to expect that in the event of an adverse reaction, the clinical trial sponsors' commitment to offer their members treatment for any medically necessary treatment would apply.

V. Out of network services are not covered, unless approved in advance by the health plan.